UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SURGICAL INSTRUMENT SERVICE COMPANY, INC., et al.,

Plaintiffs,

v.

INTUITIVE SURGICAL, INC.,

Defendant.

Case No. 21-cv-03496-AMO

ORDER RE: CROSS MOTIONS FOR SUMMARY JUDGMENT

Re: Dkt. Nos. 127, 137

FILED UNDER SEAL

This is an antitrust case related to surgical robots, their instruments, and whether the robot's manufacturer has engaged in anticompetitive conduct. This is one of two related cases before the Court alleging anticompetitive conduct by Defendant Intuitive Surgical, Inc. ("Intuitive").[1] The two cases involve similar antitrust claims – this case is brought by a competitor and the other case is brought by customers. Before the Court are the cross-motions for summary judgment of Defendant Intuitive and Plaintiff Surgical Instruments Services, Inc. ("SIS"), which were heard before this Court on September 7, 2023. Having read the papers filed by the parties and carefully considered the arguments therein and those made at the hearing, as well as the relevant legal authority, the Court hereby **GRANTS in part and DENIES in part** both motions, for the following reasons.

[1] The related case is *In Re: Da Vinci Surgical Robot Antitrust Litigation*, N.D. Cal. Case No. 3:21-cv-03825-AMO. The Court simultaneously enters its order on the pending cross-motions for summary judgment in that case.

BACKGROUND[2]

A. Intuitive's and SIS's Business Models

Intuitive manufactures sophisticated medical devices used to perform surgery. The company designs, manufactures, and sells minimally invasive surgical robots known as da Vinci Surgical Systems ("da Vinci") along with accompanying surgical instruments, called EndoWrists. EndoWrists are surgical instruments attached to the da Vinci's mechanical arms, which are suspended above the patient. Rosa Decl. ¶ 9. EndoWrists include fine wire cables that thread through a complex pulley system, allowing the surgeon to move the surgical instruments easily inside the patient's body to desired angles with great precision, mimicking and even exceeding the range of motion of the human wrist. Rosa Decl. ¶ 24.

Intuitive controls the frequency of EndoWrist instrument replacement via a built-in self-destruct mechanism it calls a "use counter." Van Hoven ("JVH") Decl. Ex. 10 at ¶ 93; Rosa Decl. ¶¶ 36-37. A simple memory chip within the EndoWrist instruments decrements every time the EndoWrist instrument is used in surgery, without regard to the actual time or rigor the EndoWrist is used in the surgery. JVH Decl. Ex. 10 ¶¶ 103-107; Rosa Decl. ¶¶ 36-37. When the use count (until recently, 10 uses in most instruments) reaches zero, the da Vinci system will no longer recognize the EndoWrist instrument, which must then be thrown away. JVH Decl. Ex. 10 ¶ 105. The use limits were described in Intuitive's submissions to the United States Food and Drug Administration ("FDA") to obtain regulatory clearance of the EndoWrist, but the parties offer conflicting evidence as to whether the limits serve any legitimate medical or patient safety purpose. *See, e.g.*, Rosa Decl. ¶¶ 22-35, 45; JVH Decl. Ex. 18 ¶¶ 22, 92-129.

Each purchaser or lessor of a da Vinci enters into a contract with Intuitive, typically a Sales, Licensing and Service Agreement ("SLSA") or corresponding lease agreement. *See* Rosa Decl. ¶ 21. Intuitive's contracts with its customers – hospitals and other surgery centers – prohibit (a) any repair or modification of EndoWrists, and (b) the use of EndoWrists beyond the maximum

[2] The Court must view the facts in the light most favorable to the non-moving party and give it the benefit of all reasonable inferences to be drawn from those facts. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 587 (1986); *Olsen v. Idaho State Bd. of Med.*, 363 F.3d 916, 922 (9th Cir. 2004).

number of uses mandated by Intuitive. *See, e.g.*, Cahoy Decl. Ex. 12 § 8. The contracts typically prohibit customers from modifying, altering, or misusing the system and its components or manipulating the software. *See, e.g.*, *id.* §§ 3.4, 4, 5.2. The agreements confirm that the da Vinci system should be used only with approved EndoWrists and provide that use of a non-approved instrument may give Intuitive the right to discontinue service. *Id.* Intuitive also disclaims warranty obligations for claims arising from repairs, modifications, or other changes made by a third party. *See, e.g.*, *id.* §§ 5.2(E), 10.1.

Da Vinci systems have evolved over time, and Intuitive has periodically introduced new models, with support eventually being phased out for outdated models. The first da Vinci systems were introduced commercially in the United States in 2000, after the FDA granted the da Vinci system and the instruments used with it clearance as medical devices that can be marketed and used on patients. Rosa Decl. ¶ 8. The "Si" da Vinci systems were introduced in 2009; Intuitive ceased selling new Si systems in the United States in 2018 and is expecting to cease support for those systems, including the sale of new S/Si EndoWrists, in 2024, ten years after introducing the successor Xi model. Rosa Decl. ¶ 11; Cahoy Decl. Ex. 2 at 172:13-174:12. The models that are primarily used today in the United States are the Xi, introduced in 2014, and the X, introduced in 2017. Rosa Decl. ¶ 11. By early 2019, medical technology companies such as Rebotix Repair ("Rebotix")and Restore Robotics ("Restore") had made significant sales of repaired S/Si EndoWrists to a number of hospitals and systems in the United States. JVH Decl., Ex. 8 at 74:19-76:17. Those companies circumvented the S/Si use counter and performed an inspection and repair process to ensure that the repaired instrument would operate in the same manner as an Intuitive-provided device. JVH Decl. Ex. 10 ¶¶ 68-91. In significant part, Rebotix developed a computer chip called the "Interceptor" that could be inserted inside the S/Si EndoWrists to "intercept" the data in the EndoWrist's memory and fool the system into accepting a new use count starting at zero. *See* Cahoy Decl. Ex. 14 at 6.

SIS provides servicing of surgical instruments ranging from stainless instruments to more complex systems such as surgical video systems and flexible endoscopes. JVH Decl. Ex. 17 at 2; Ex. 18 at 11:20-12:1. SIS became aware of Rebotix's repair procedure for the EndoWrist in

spring of 2019, and over the ensuing months, SIS worked with Rebotix to understand the process and potentially bring it to SIS customers. JVH Decl. Ex. 18 at 23:18-27:20; Ex. 20 at 23:9-24:16, 32:21-33:18. SIS began offering reset S/Si EndoWrists to its customer base in fall of 2019. JVH Decl. Ex. 20 at 109:9-18, 110:13-24, 116:1-9; Ex. 8 at 88:7-19. SIS signed an agreement specific to EndoWrist repairs with Vizient, the country's largest group purchasing organization (GPO) representing thousands of hospitals and health care facilities. JVH Decl. Ex. 19 at 52:5-53:8; Ex. 20 at 87:2-6; Ex. 18 at 77:14-78:20. Hospital demand for the EndoWrist repair service was "monumental," with interest from several hospitals and hospital systems across the country. JVH Decl. Ex. 20 at 44:7-45:22; Ex. 19 at 50:10-51:24.

Intuitive sent letters to virtually every hospital where it discovered use of repaired EndoWrists, including to SIS's customers, reminding them of the terms of the SLSAs and threatening to cut off those customers' access to ongoing support and service from Intuitive. *See, e.g.*, JVH Decl. Ex. 8 at 79:18-81:15, 88:7-19, 92:17-94:7; Ex. 24; Ex. 25. Faced with the shutdown of their robotic surgery programs, all SIS customers (and to SIS's knowledge, all EndoWrist repair customers) stopped using repaired EndoWrists. JVH Decl. Ex. 18 at 39:21-40:5, 41:23-44:19; Ex. 19 at 55:12-56:7; Ex. 22 at 39:3-41:4.

B. FDA & Section 510(k) Clearance

The da Vinci robot and EndoWrist instruments fit within a regulatory scheme that shapes the parties' arguments in the pending motions. The Food, Drug and Cosmetic Act ("FDCA"), as amended by the Medical Device Amendments of 1976 ("MDA"), 90 Stat. 539 (codified at 21 U.S.C. § 301 et seq.), requires that medical devices like the da Vinci and its components receive certain approvals from the United States Food and Drug Administration ("FDA"). "The MDA separates devices into three categories: Class I devices are those that present no unreasonable risk of illness or injury and therefore require only general manufacturing controls; Class II devices are those possessing a greater potential dangerousness and thus warranting more stringent controls; Class III devices present a potential unreasonable risk of illness or injury and therefore incur the FDA's strictest regulation." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001) (internal quotation marks and alteration omitted). Manufacturers or remanufacturers of Class II

devices need only submit a "premarket notification" to the FDA in accordance with the less burdensome "510(k) process" rather than the more rigorous process of obtaining "premarket approval" from the FDA necessary for manufacturers of Class III devices. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477-79 (1996) (contrasting the two procedures); *see also* 21 C.F.R. § 807.81(a). "Section 510(k)" refers to the section of the original MDA containing this provision, and it sets forth the procedure by which a medical device that is "substantially equivalent" to a device that is already on the market can be cleared for sale without undergoing the more rigorous pre-market review and approval process. *See* 21 U.S.C. § 360(k); *see also Medtronic*, 518 U.S. at 478-79.[3]

The parties disagree as to whether SIS's and other third parties' services require Section 510(k) clearance from the FDA, and the FDA's position on the matter is less than clear. Rebotix first sought regulatory clearance of its procedure in December 2014. Cahoy Decl. Ex. 10 ¶ 103; Ex. 21. FDA responded by identifying deficiencies in the application and warning Rebotix that it could not place remanufactured instruments into commercial distribution unless and until it received FDA clearance. Cahoy Decl. Ex. 23. Rather than addressing the deficiencies identified by FDA, Rebotix withdrew its application. Cahoy Decl. Ex. 24.

Rebotix then implemented a new business model, beginning in 2018: hospitals retained ownership of their used Si EndoWrists and hired Rebotix to modify the instruments. Cahoy Decl. Ex. 20 at 210:9-21, 227:10-23. In furtherance of that model, Rebotix entered into a relationship with Restore Robotics ("Restore"), for Restore to market the Rebotix process to hospitals, buy the Interceptor chips from Rebotix, and modify the instruments. Cahoy Decl. Ex. 28. Rebotix terminated the contract in late 2019. Cahoy Decl. Ex. 20 at 132:12-21. Rebotix also entered into

[3] "Remanufacturer" is defined in the Federal Regulations as "any person who processes, conditions, renovates, repackages, restores, or does any other act to a finished device that significantly changes the finished device's performance or safety specifications, or intended use." 21 C.F.R. § 820.3(w). Because there is a dispute about whether SIS's treatment of the EndoWrists constitutes "repair" or "remanufacturing" and the term of art used has implications for the outcome of the case, the Court generally refers to the treatment as "service" to the extent possible in this order.

an arrangement with SIS under which SIS would market the Rebotix service to hospitals and Rebotix would perform the modifications. *Id.* Ex. 29 at 19:2-8, 33:22-34:4.

Following an inquiry from a Rebotix distributor, FDA stated that Section 510(k) clearance was required because "if the use-life counter is reset or extended past the number of available use lives, then the device specifications are changed," which would constitute "remanufactur[ing]." Cahoy Decl. Ex. 31 at -0335. That correspondence also stated that the message constituted "an informal communication" that did "not necessarily represent the formal position of FDA, and [did] not bind or otherwise obligate or commit the agency to the view expressed." *Id.* at -0335-36. In February 2020, an FDA representative emailed Rebotix directly, stating that "a 510(k) is needed before [Rebotix] continue[s] [its] operation." Cahoy Decl. Ex. 34 at -6955. Following further communications with the agency, Restore informed the agency that it had elected to exit the business. Cahoy Decl. Ex. 38 at -1249.

Restore then worked with a third party, Iconocare, to submit an application for FDA clearance. Cahoy Decl. Ex. 39 at 204:16-205:17, 213:19-216:23. Iconocare hired contractors to develop an alternative technology and then, in February 2021, submitted a 510(k) application for that new process which differed from the Rebotix process in important respects. *Id.* Ex. 39 at 213:9-15; Ex. 75 ¶¶ 141-50. FDA conducted an extensive review process that required additional testing and procedural adjustments by Iconocare, and on September 30, 2022, Iconocare received clearance on its limited application. Cahoy Decl. Ex. 10 ¶ 136. In the course of granting this clearance, FDA repeatedly described the modification to reset the use counter as "remanufacturing," which required 510(k) clearance. Cahoy Decl. Ex. 10 ¶¶ 129, 136; Ex. 41 at -0535; Ex. 42 (ECF 138-28) at -6093.

Separately, in Rebotix's communications with FDA regarding its activities, the company received email correspondence from a Team Lead at the FDA stating as follows:

> As mentioned during our call, the Agency believes that the activities of Rebotix constitute remanufacturing and would require FDA review and clearance (e.g. 510(k) / de Novo). We therefore request that Rebotix stop engaging in the current activities until an application is reviewed and cleared/granted.

> The instruments in question no longer maintain the same safety and effectiveness profile as cleared with the original manufacturer's own submission. During premarket review, FDA reviews test data to the labeled number of reuse cycles. This includes, but is not limited to, items such as electrical safety, reprocessing, software, and general performance testing. By extending the number of uses and modifying the instrument with a new chip, the prior information is no longer valid and requires additional review to the new labeled usage limit in order to establish safety and effectiveness. This is therefore different than returning the device to its original condition.

Cahoy Ex. 37 (email dated April 8, 2022).[4] In response to this correspondence from FDA, Rebotix mentioned that it would appeal FDA's regulatory determination that the EndoWrist services constituted remanufacturing, to which the same Team Lead clarified that his message was not an "official regulatory evaluation." *Id.* (email dated July 22, 2022). Rather, the correspondence represented informal comments following a "preliminary informal assessment" of limited materials and did "not represent the formal position of FDA" or any position that was appealable. *Id.*

C. Procedural History

1. Earlier Lawsuits

In 2019, Restore Robotics, LLC, filed suit against Intuitive in the Northern District of Florida. Restore alleged that Intuitive engaged in anti-competitive conduct, using its monopoly power in the surgical robot market to further monopolize EndoWrist repair and replacement markets. That case was heavily litigated, including through cross-motions for summary judgment that resemble the motions filed in the instant case. The court mostly denied summary judgment, noting that "the jury will have to resolve this 'battle of the experts.'" *Restore Robotics, LLC v. Intuitive Surgical, Inc.*, No. 5:19CV55-TKW-MJF, 2022 WL 1495005 (N.D. Fla. Apr. 11, 2022). The case settled less than two weeks before the trial date.

In 2020, Rebotix Repair, LLC, filed suit against Intuitive in the Middle District of Florida. Rebotix advanced similar claims that Intuitive engaged in anti-competitive conduct. That case

[4] This correspondence was submitted under seal. However, the Court provides this portion of the correspondence in its public order because it has already been made public in another case, *Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, No. 8:20-CV-2274-VMC-TGW, 2022 WL 3272538 (M.D. Fla. Aug. 10, 2022), discussed further below.

was also heavily litigated, including through cross-motions for summary judgment that resemble the motions filed in the instant case. The court more plainly denied summary judgment to both sides, noting that a jury would have to weigh the competing expert testimony and evidence about the allegedly anti-competitive conduct. *Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, No. 8:20-CV-2274-VMC-TGW, 2022 WL 3272538 (M.D. Fla. Aug. 10, 2022). The case settled a month after the order denying summary judgment issued, shortly prior to the final pretrial conference.

2. SIS's Lawsuit and Cross-Motions

SIS filed suit against Intuitive in this district on May 1, 2021. ECF 1. SIS brings Sherman Act and Lanham Act claims against Intuitive, claiming that SIS's business was harmed because Intuitive conditions the sale and servicing of its da Vinci surgical robots on customers buying replacement EndoWrists from Intuitive rather than permitting customers to use repaired EndoWrists. SIS claims that Intuitive's actions violate the antitrust laws. First, SIS asserts that the contractual constraints Intuitive places on its customers – which together prohibit customers from having their EndoWrist instruments refurbished by third parties – constitute a "restraint of trade" in violation of Section 1 of the Sherman Act. 15 U.S.C. § 1. Second, SIS alleges that Intuitive violated Section 2 of the Sherman Act, 15 U.S.C. § 2, through a series of exclusionary tactics, including "tying EndoWrist replacements and repairs to sales and servicing of da Vinci surgical robots," sending cease and desist letters when customers attempted to have their EndoWrist instruments refurbished by third parties, and redesigning its instruments to prevent third-party services from resetting the use counter on its instruments. Finally, SIS brings an attempted monopolization claim under Section 2 based on this same conduct.

SIS also asserts that Intuitive violated the Lanham Act by making false and misleading statements to its customers. 15 U.S.C. § 1125. SIS raises two Lanham Act claims based on two sets of Intuitive's alleged statements: that SIS's services require FDA approval and that SIS's services violate Intuitive's intellectual property rights.

Judge Chhabria denied Intuitive's Motion to Dismiss (ECF 70), and Intuitive filed an answer to the complaint that included the affirmative defense of unclean hands (ECF 75). Intuitive's unclean hands defense alleges in part that "SIS's claims are barred, in whole or in part,

by the doctrine of unclean hands because SIS has acted contrary to applicable FDA regulations . . . ." ECF 75 at 39 ("First Defense"). In addition, Intuitive alleges five counterclaims against SIS, including of an unfair competition and false advertising claim under the Lanham Act (Count 1) and its derivative claims for violation of California's Unfair Competition Law (Count 2), violation of California's False Advertising Law (Count 3), and common law unfair competition (Count 4).[5] The counterclaims, like the unclean hands defense, rely on allegations that "SIS has made numerous false and misleading statements, including . . . that the 'repair' and/or resulting instruments do not require clearance by the FDA[.]" *Id.* at ¶¶ 85, 93, 99, 102.

The instant motions were filed starting in March 2023. In the first brief filed, SIS does not move for summary judgment on its own claims; rather, it seeks summary judgment regarding Intuitive's counter claims and single affirmative defense – both sides aver that the resolution of whether FDA clearance is necessary for SIS's servicing of EndoWrists will resolve the motion. SIS moves for partial summary judgment in its favor on Intuitive's affirmative defense of unclean hands, as well as Intuitive's Lanham Act counterclaim and its three derivative state law counterclaims. Intuitive's cross-motion seeks summary judgment on the entirety of SIS's complaint.

LEGAL STANDARD

A party may move for summary judgment on a "claim or defense" or "part of . . . a claim or defense." Fed. R. Civ. P. 56(a). Summary judgment is appropriate when there is no genuine dispute as to any material fact and the moving party is entitled to judgment as a matter of law. *Id.* The party seeking summary judgment bears the initial burden of informing the court of the basis for its motion, and of identifying those portions of the pleadings and discovery responses that demonstrate the absence of a genuine issue of material fact. *Celotex Corp. v. Catrett*, 477 U.S. 317, 323 (1986). Material facts are those that might affect the outcome of the case. *Anderson v.*

[5] Intuitive's fifth counterclaim alleges tortious interference with contract. Because neither party specifically seeks adjudication of that counterclaim through the briefing underlying this order, the Court does not address it.

Liberty Lobby, Inc., 477 U.S. 242, 248 (1986). A dispute as to a material fact is "genuine" if there is sufficient evidence for a reasonable jury to return a verdict for the nonmoving party. *Id.*

Where the moving party will have the burden of proof at trial, it must affirmatively demonstrate that no reasonable trier of fact could find other than for the moving party. *Soremekun v. Thrifty Payless, Inc.*, 509 F.3d 978, 984 (9th Cir. 2007). On an issue where the nonmoving party will bear the burden of proof at trial, the moving party may carry its initial burden of production by submitting admissible "evidence negating an essential element of the nonmoving party's case," or by showing, "after suitable discovery," that the "nonmoving party does not have enough evidence of an essential element of its claim or defense to carry its ultimate burden of persuasion at trial." *Nissan Fire & Marine Ins. Co., Ltd. v. Fritz Cos., Inc.*, 210 F.3d 1099, 1105-06 (9th Cir. 2000); *see also Celotex*, 477 U.S. at 324-25 (moving party can prevail merely by pointing out to the district court that there is an absence of evidence to support the nonmoving party's case).

When the moving party has carried its burden, the nonmoving party must respond with specific facts, supported by admissible evidence, showing a genuine issue for trial. Fed. R. Civ. P. 56(c), (e). The asserted disputed facts must be material – the existence of only "some alleged factual dispute between the parties will not defeat an otherwise properly supported motion for summary judgment." *Anderson*, 477 U.S. at 247-48.

When deciding a summary judgment motion, a court must view the evidence in the light most favorable to the non-moving party and draw all justifiable inferences in its favor. *Id.* at 255; *Hunt v. City of Los Angeles*, 638 F.3d 703, 709 (9th Cir. 2011). However, when a non-moving party fails to produce evidence rebutting defendants' showing, then an order for summary adjudication is proper. *Nissan Fire*, 210 F.3d at 1103 ("If the nonmoving party fails to produce enough evidence to create a genuine issue of material fact, the moving party wins the motion for summary judgment."). The court's function on a summary judgment motion is not to make credibility determinations or weigh conflicting evidence with respect to a disputed material fact. *See T.W. Elec. Serv., Inc., v. Pac. Elec. Contractors Ass'n*, 809 F.2d 626, 630 (9th Cir. 1987).

DISCUSSION

SIS seeks partial summary judgment as to Intuitive's four false advertising counterclaims as well as its affirmative defense of unclean hands. SIS does not seek summary judgment as to the causes of action it presents in its own operative complaint. Intuitive, on the other hand, seeks summary judgment in its favor as to all the causes of action in SIS's operative complaint. The Court addresses the arguments presented in SIS's motion first.

I. SIS'S MOTION FOR SUMMARY ADJUDICATION

SIS argues that those of Intuitive's counterclaims and affirmative defenses that rely on establishing a violation of the FDCA should all be dismissed. Intuitive's Lanham Act counterclaim and derivative state law claims are all premised on the alleged falsity of SIS's statements that "repaired" EndoWrist instruments do not require clearance by the FDA. The Court first addresses Intuitive's false advertising counterclaims before turning to the affirmative defense of unclean hands.

A. Intuitive's False Advertising Counterclaims[6]

Intuitive's unfair competition and false advertising claim under the Lanham Act (Count 1) and its derivative state law claims (Counts 2-4) all require Intuitive to establish that SIS made a false and misleading statement to its customers. *See, e.g.*, *Skydive Arizona, Inc. v. Quattrocchi*, 673 F.3d 1105, 1110 (9th Cir. 2012) (citing 15 U.S.C. § 1125(a)(1)(B); *Southland Sod Farms v. Stover Seed Co.*, 108 F.3d 1134, 1139 (9th Cir. 1997)). Intuitive alleges in part that "SIS has made numerous false and misleading statements, including . . . that the 'repair' and/or resulting instruments do not require clearance by the FDA." ECF 75 ¶ 85. SIS argues that its statements about not needing FDA clearance cannot be deemed false or misleading where FDA has not taken any enforcement action and has avoided defining whether SIS's services constitute remanufacturing, which would require Section 510(k) clearance. Essentially, Intuitive asks the Court to determine whether SIS's aftermarket EndoWrist-related services required Section 510(k)

[6] The Court's analysis and conclusion in this section are substantially similar to the analysis and discussion in the Court's order in the related case, *In Re: Da Vinci Surgical Robot Antitrust Litigation*, N.D. Cal. Case No. 3:21-cv-03825-AMO, also entered today.

clearance from the FDA. However, this query is problematic because "[t]he FDCA [(Food, Drug and Cosmetic Act)] leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001).

Indeed, a private action brought under the Lanham Act may not be pursued when it requires litigating an alleged underlying FDCA violation where the FDA has not itself concluded that a violation exists. *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 924 (9th Cir. 2010) (affirming grant of summary judgment for defendant on Lanham Act false advertising claim where FDA had not taken a position on defendant's laser's need for Section 510(k) clearance, and claim was based on defendant allegedly misrepresenting that its laser had received FDA clearance). To be sure, the FDCA does not preclude all Lanham Act claims. *See POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 120 (2014) (permitting a Lanham Act claim challenging FDA-regulated food label as misleading). However, courts have consistently precluded private actions which require establishing a violation of the FDCA.[7] *See, e.g., Amarin Pharma, Inc. v. International Trade Commission*, 923 F.3d 959, 968 (Fed. Cir. 2019) (citing *PhotoMedex*, 601 F.3d at 924, 928) (finding that Lanham Act claim could not stand where it was "based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA.").

Intuitive's Lanham Act and derivative state law counterclaims ask the Court to determine whether the aftermarket EndoWrist services constituted "remanufacturing" and whether SIS violated 21 C.F.R. § 807.81 by offering its services to consumers without first obtaining Section 510(k) clearance. However, the FDA has expressly disclaimed concluding that a violation exists, and it has taken no final position on the need for 510(k) clearance here. *See, e.g.*, Cahoy Decl. Ex.

[7] In his order denying Intuitive's motion to dismiss earlier in this case, Judge Chhabria concluded that *POM Wonderful* had "effectively overruled" *PhotoMedex*. *Surgical Instrument Serv. Co., Inc. v. Intuitive Surgical, Inc.*, 571 F. Supp. 3d 1133, 1142 (N.D. Cal. 2021). However, that no longer appears to be the case, as the Ninth Circuit has restated its continued fidelity to the principle that the FDA maintains exclusive enforcement authority over the FDCA. *Nexus Pharms., Inc. v. Cent. Admixture Pharmacy Servs., Inc.*, 48 F.4th 1040, 1048 (9th Cir. 2022) (citing *PhotoMedex*, 601 F.3d at 926-28).

37 (email from FDA Team Lead clarifying that his message was not an "official regulatory evaluation" and did "not represent the formal position of FDA"). Despite Intuitive's repeated entreaties for the Court to find that informal communications made FDA's position clear, that is not so.[8] The Court, as others before it, declines Intuitive's invitation to step into the FDA's shoes and determine whether SIS's services require 510(k) clearance. *See Rebotix Repair, LLC v. Intuitive Surgical, Inc.*, No. 8:20-CV-2274-VMC-TGW, 2022 WL 3272538, at *5 (M.D. Fla. Aug. 10, 2022); *Restore Robotics, LLC v. Intuitive Surgical, Inc.*, No. 5:19-cv-55-TKW-MJF, 2019 WL 8063988, at *2-3 (N.D. Fla. Nov. 14, 2019) (finding this determination more properly within the exclusive purview of FDA). Because FDA has not determined whether 510(k) clearance is necessary for SIS's aftermarket EndoWrist services, Intuitive may not proceed with its claims premised on SIS's representations that Section 510(k) clearance was not necessary, as that requires litigating an alleged FDCA violation. Intuitive's counterclaims, all of which rely on regulatory interpretation left to the FDA in the first instance, thus fail as a matter of law.

Although presented as causes of action relying on different legal authority, Intuitive's Lanham Act counterclaim, along with its derivative state law claims, constitute an attempt to enforce the FDCA and its implementing regulations. Private parties have no such enforcement authority, and the counterclaims that rely on proving a violation of the FDCA cannot proceed. Therefore, the Court GRANTS SIS's motion for summary adjudication on Intuitive's false advertising counterclaims.

B. Unclean Hands Defense

SIS also moves for summary judgment on Intuitive's unclean hands defense. The doctrine of unclean hands is a "maxim that 'he who comes into equity must come with clean hands.'" *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814 (1945). Unclean hands "bars relief to a plaintiff who has violated conscience, good faith or other equitable principles in his prior conduct." *Dollar Sys., Inc. v. Avcar Leasing Sys., Inc.*, 890 F.2d 165, 173

[8] This Court is in good company concluding that these informal communications do not constitute a final FDA action. *See Restore Robotics*, 2019 WL 8063988, at *2-3; *Rebotix Repair*, 2022 WL 3272538, at *5.

(9th Cir. 1989). The doctrine "requires a finding of inequitableness or bad faith." *Rent-A-Ctr., Inc. v. Canyon Television & Appliance Rental, Inc.*, 944 F.2d 597, 602 (9th Cir. 1991). Further, it "requires balancing the alleged wrongdoing of the plaintiff against that of the defendant." *Northbay Wellness Grp., Inc. v. Beyries*, 789 F.3d 956, 960 (9th Cir. 2015). Though the party against whom unclean hands is enforced need not have acted unlawfully, the court may only apply the doctrine where the party committed a "willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct." *Precision Instrument Mfg. Co.*, 324 U.S. at 815.

SIS argues that the defense of unclean hands in the Lanham Act context requires a showing that the other party's conduct was "inequitable" or "unconscionable," neither of which applies to its conduct here. SIS contends that it cannot have "willfully" violated FDA regulations where the FDA has not clarified what constitutes remanufacturing and has avoided deciding whether SIS's EndoWrist services constitute remanufacturing. Intuitive counters that there is no ambiguity, that FDA has consistently communicated that SIS's EndoWrist services constitute remanufacturing for which Section 510(k) clearance is necessary.

The Court agrees with SIS. Given the conclusion reached in the section above, the Court cannot find that SIS acted wrongfully by providing aftermarket EndoWrist services. The evidence demonstrates that SIS acted with good faith in its EndoWrist services. Since the time it entered the EndoWrist service market, SIS operated under a reasonable interpretation of the relevant regulations and made its position clear: "The da Vinci® EndoWrist® is a 'multi-use' medical device. Multi-use devices, such as endoscopic instruments, have always been eligible for repair." JVH Decl. Ex. 21 at 6 (SIS095124). As explained by SIS at the time, "The FDA does not regulate, nor certify, repairs. The FDA regulates third party reprocessing companies and single-use devices only." *Id.* at 2 (SIS095120). Although Intuitive presents ample evidence that it disagrees with SIS's interpretation of the relevant regulations in finding that its service constituted repairs (*see, e.g.*, Cahoy Decl. 10 ¶ 176, Ex. 65 at 18), Intuitive does not provide any evidence establishing that SIS acted with unclean hands. Therefore, the Court GRANTS SIS's motion for summary adjudication on Intuitive's affirmative defense of unclean hands.

II. INTUITIVE'S MOTION FOR SUMMARY JUDGMENT

Because the discussion in the preceding section informs the merits of SIS's Lanham Act claim against Intuitive, the Court considers Intuitive's motion for judgment on that claim next. The Court then turns to Intuitive's related arguments regarding SIS's alleged antitrust injury. The Court finally analyzes the merits of Intuitive's challenge to SIS's antitrust claims.

A. SIS's Lanham Act Claim

SIS's Lanham Act Claim, similar to the Intuitive claim discussed above, is premised on the alleged falsity of statements regarding the necessity of Section 510(k) clearance for aftermarket EndoWrist services. SIS's Lanham Act claim rests on its assertion that Intuitive, in correspondence with SIS customers, "misrepresented that SIS's services are contrary to FDA approvals of the EndoWrist products." ECF 1 ¶¶ 123-24; *see also* Cahoy Decl. Exs. 82, 83. The Court found above that Intuitive's Lanham Act claim against SIS could not stand because it would require deciding whether Section 510(k) clearance was required, which would constitute private enforcement of the FDCA. The same reasoning applies to SIS's Lanham Act claim against Intuitive. The Court cannot resolve this issue as a matter of law, and the Court therefore dismisses SIS's Lanham Act claim against Intuitive.

B. Antitrust Injury

Intuitive seeks summary adjudication on the issue of whether SIS suffered antitrust injury. SIS avers that it suffered antitrust injury by its exclusion from the market for EndoWrist repair and replacement – there was substantial demand for SIS's services until Intuitive threatened to shut down hospital robot programs, among other allegedly anticompetitive conduct. *See, e.g.*, JVH Decl. Ex. 20 44:7-45:22; Ex. 19 at 50:10-51:24 (describing hospital demand for the EndoWrist repair service as "monumental"). Intuitive argues here that the robot producer's conduct was not the reason that SIS was excluded from the EndoWrist repair and replacement market; rather, SIS was excluded from that market because applicable regulations required SIS to obtain agency clearance before offering such services. Said another way, Intuitive contends that it was SIS's failure to first obtain Section 510(k) clearance from the FDA that restrained SIS's aftermarket

EndoWrist servicing business, and any conduct by Intuitive thus did not proximately cause antitrust injury to SIS.

In the Ninth Circuit, a plaintiff must satisfy four requirements to show antitrust injury: "(1) unlawful conduct, (2) causing an injury to the plaintiff, (3) that flows from that which makes the conduct unlawful, and (4) that is of the type the antitrust laws were intended to prevent." *City of Oakland v. Oakland Raiders*, 20 F.4th 441, 456 (9th Cir. 2021) (citation omitted). Antitrust injury cannot be proved where the claimed injury "is caused by a regulatory scheme rather than by the defendant's actions, as it is "beyond fair dispute" that "a regulatory or legislative bar can break the chain of causation in an antitrust case." *In re Wellbutrin XL Antitrust Litig. Indirect Purchaser Class*, 868 F.3d 132, 165-66 (3d Cir. 2017). For example, in *Modesto Irrigation Dist. v. Pac. Gas & Elec. Co.*, 309 F. Supp. 2d 1156, 1170 (N.D. Cal. 2004), *aff'd sub nom. Modesto Irrigation Dist. v. Pac. Gas & Elec. Co.*, 158 F. App'x 807 (9th Cir. 2005), the plaintiff, an irrigation district, complained that Pacific Gas & Electric had interfered with its attempt to offer competing electric service in Pittsburg, California. The district court held that the plaintiff could not prove antitrust injury because it "possessed neither the legal right, nor the necessary [regulatory agency] permission to expand its services into Pittsburg." *Modesto Irrigation Dist.*, 309 F. Supp. 2d at 1170. And "[b]ecause [the plaintiff's] conduct was unlawful by its own terms, PG&E's response – however anti-competitive or seemingly monopolistic – could not inflict [a] cognizable antitrust injury." *Id.*

Intuitive analogizes to *Modesto Irrigation District*, positing that SIS is barred from providing aftermarket EndoWrist services without Section 510(k) clearance in the same way that the plaintiff utility company faced a regulatory bar from offering its services in Pittsburg, California. However, as discussed above, this Court will not permit Intuitive to seek private enforcement of the FDCA, an issue upon which Intuitive's argument against injury causation rests. In contrast to *Modesto Irrigation District*, Plaintiff SIS has not clearly engaged in unlawful conduct and accordingly may still seek to prove that Intuitive's anticompetitive conduct caused its antitrust injury at trial. Therefore, the Court DENIES Intuitive's motion for summary judgment on this basis.

C. Antitrust Claims

In addition to seeking judgment as a matter of law on antitrust injury, Intuitive asks the Court to grant it judgment on the merits of SIS's antitrust claims. While a threshold step in any antitrust analysis is to accurately define the relevant market, which refers to "the area of effective competition," *Ohio v. Am. Express Co.*, 585 U.S. 529, 543 (2018) (citation omitted), the parties here do not appear to dispute the market at issue, nor does SIS assert that the alleged restraints here are *per se* unreasonable. Their arguments focus on whether the parties can satisfy the respective burdens imposed by the rule of reason. *See Flaa v. Hollywood Foreign Press Ass'n*, 55 F.4th 680, 688 (9th Cir. 2022).

The rule of reason calls on courts to conduct a fact-specific assessment of market power and structure to assess a restraint's actual effect on competition. *Fed. Trade Comm'n v. Qualcomm Inc.*, 969 F.3d 974, 991 (9th Cir. 2020). Under the rule of reason's framework:

> the plaintiff has the initial burden to prove that the challenged restraint has a substantial anticompetitive effect that harms consumers in the relevant market. If the plaintiff carries its burden, then the burden shifts to the defendant to show a procompetitive rationale for the restraint. If the defendant makes this showing, then the burden shifts back to the plaintiff to demonstrate that the procompetitive efficiencies could be reasonably achieved through less anticompetitive means.

Am. Express, 585 U.S. at 541 (citing 1 Kalinowski § 12.02[1]; P. Areeda & H. Hovenkamp, Fundamentals of Antitrust Law § 15.02[B] (4th ed. 2017); *Capital Imaging Assoc., P.C. v. Mohawk Valley Med. Assocs., Inc.*, 996 F.2d 537, 543 (2nd Cir. 1993)).

Intuitive only challenges SIS on the second and third steps. The Court considers the arguments presented in the parties' briefing regarding the second step of the rule of reason analysis and, in so doing, assumes without deciding that SIS can carry its initial burden of showing the anticompetitive effects of Intuitive's conduct for purposes of this discussion.

A procompetitive rationale is a "nonpretextual claim that [defendant's] conduct is indeed a form of competition on the merits because it involves, for example, greater efficiency or enhanced consumer appeal." *Qualcomm*, 969 F.3d at 991. It is not enough that "conduct 'has the effect of reducing consumers' choices or increasing prices to consumers.'" *Id.* at 990 (quoting *Brantley v.*

NBC Universal, Inc., 675 F.3d 1192, 1202 (9th Cir. 2012)). For example, the Ninth Circuit affirmed a finding that Apple "offered non-pretextual, legally cognizable procompetitive rationales for its" anticompetitive conduct, including restrictions it imposed to promote user privacy and security. *Epic Games, Inc. v. Apple, Inc.*, 67 F.4th 946, 985, 987-89 (9th Cir. 2023), cert. denied, 144 S. Ct. 681 (2024), and cert. denied, 144 S. Ct. 682 (2024).

Intuitive argues that the antitrust laws do not penalize a defendant that had a "reasonable basis to conclude that its [challenged] actions were necessitated by concrete factual imperatives recognized as legitimate by the regulatory authority." *Phonetele, Inc. v Amer. Tel. & Tel. Co.*, 664 F.2d 716, 737-38 (9th Cir. 1981); *see also In re Lantus Direct Purchaser Antitrust Litig.*, 950 F.3d 1, 12 (1st Cir. 2020) (regulatory justification defense can defeat antitrust claim if defendant's decision was reasonable and made in good faith). Intuitive asserts that it had a reasonable basis for concluding that EndoWrist use limits were necessary, a conclusion affirmed by the FDA in its initial approval of the instruments. The same reasoning underlies Intuitive's efforts to ensure that the use limits were not circumvented, it contends, including letters sent to customers and the FDA, and thus that it had a reasonable basis to act, satisfying the second step.

Intuitive's argument regarding its "legitimate justifications" for anticompetitive conduct misstates what the rule of reason requires and thus short-circuits. To the extent Intuitive argues that its anticompetitive behavior arose from a good-faith attempt to ensure patient safety and compliance with FDA regulations, it has failed to provide a nonpretextual "procompetitive rationale." *See Qualcomm*, 969 F.3d at 991. Intuitive claims that its conduct related to the EndoWrist market has certain benefits, including ensuring product reliability and minimizing risks to patients. Rosa Decl. ¶¶ 28-33 (describing EndoWrist testing to mitigate instrument failure). Although patient safety appears to be an important rationale for the manufacture of surgical robots, SIS argues that such justification amounts to mere pretext. Indeed, SIS proffers conflicting evidence regarding the patient safety justifications for Intuitive's use limits. *See* JVH Decl., Ex. 11 (Mahal Report) ¶¶ 20-21, 53-66; JVH Decl. Ex. 18 (Parnell Report) ¶¶ 22, 92-129 (contradicting safety justification for EndoWrist use counter). The directly conflicting evidence regarding the potential benefits of Intuitive's conduct is best left for a jury to weigh. *See Nat'l*

Collegiate Athletic Ass'n v. Alston, 594 U.S. 69, 97 (2021) (providing that the rule of reason allows for a factfinder to holistically weigh "all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition."). Accordingly, the Court finds that Intuitive is not entitled to summary adjudication on the issue of its procompetitive rationale.

Because Intuitive fails to identify any nonpretextual procompetitive justifications, the Court does not reach the issue of whether SIS can demonstrate the existence of less restrictive alternatives. Intuitive is not entitled to summary judgment on SIS's antitrust claims.

CONCLUSION

For the foregoing reasons, the Court **GRANTS in part and DENIES in part** SIS's motion. Intuitive's false advertising counterclaims, including Counts One through Four are **DISMISSED**. Additionally, the Court **GRANTS** SIS's motion for summary adjudication on Intuitive's affirmative defense of unclean hands. The Court **GRANTS in part and DENIES in part** Intuitive's motion. SIS's Lanham Act claim is **DISMISSED**. SIS's antitrust claims will proceed to trial.

The Court resolves Intuitive's several motions to exclude expert testimony as well as the parties' several administrative motions to seal in separate orders.

This Order is filed under seal. The parties shall meet and confer with each other and any appropriate non-parties, and on or before April 26, 2024, submit a new proposed redacted version of this Order that incorporates the Court's rulings on the administrative motions to seal.

IT IS SO ORDERED.

Dated: March 31, 2024

ARACELI MARTÍNEZ-OLGUÍN
United States District Judge